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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,674	11/13/2003	Ken Y. Lin	STAN-276	9855
24353	7590	02/08/2005	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			VENC, DAVID J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/713,674	Applicant(s) LIN ET AL.	
	Examiner David J Venci	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on September 27, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/04/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, drawn to a method, classified in class 435/114, for example.
- II. Claims 10-14, drawn to products, classified in class 530/387.9, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of Invention II can be used in a materially different process of making an affinity resin.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

On Wednesday, February 2, 2004, Attorney Paula Borden telephonically elected to prosecute Invention I, claims 1-9, without traverse. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 1 is incomplete because it is not clear how merely "contacting a sample with an α -dicarbonyl compound" results in ADMA detection, or whether/how "contacting a sample with an α -dicarbonyl compound" is directly involved in detection. In addition, claim 1 is incomplete because it is not clear what step(s) or structure(s) is/are required for "detecting ADMA in the sample" or whether there is a causal relationship between "contacting a sample with an α -dicarbonyl compound" and the step(s) required for "detecting ADMA in the sample."

In claim 3, the recitation of "modified" is indefinite because it is not clear how the α -amino group of SDMA, ADMA, and arginine are "modified" or what step(s) is/are required for modification. In addition, the overall purpose of the step of claim 3 in the method of claim 1 is not clear.

In claim 5, the recitation of "contacting the sample with an antibody that binds specifically to dimethylarginines, wherein said antibody does not bind to the modified SDMA" is seemingly contradictory because it appears that "modified SDMA", i.e. modified symmetrical dimethylarginine, is a dimethylarginine. Therefore, it is not clear why said antibody does not bind to modified SDMA.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balint & Cooke (WO 98/49199) in view of Duerksen & Wilkinson, 160 ANAL. BIOCHEM. 444 (1987).

Balint & Cooke teach a method of detecting ADMA (see Abstract) in a sample comprising ADMA, SDMA, and arginine (see p. 18, lines 5-7) comprising the step of detecting ADMA (see Abstract). Balint & Cooke do not teach the step of "contacting the sample with an α -dicarbonyl compound."

However, Duerksen & Wilkinson teach the use of an α -dicarbonyl compound (see Abstract, "4-(Oxoacetyl)phenoxyacetic acid (OAPA)") as a linker for immobilizing arginine-containing compounds to solid phases (see p. 444, col. 1, "solid supports"). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the method of detecting ADMA of Balint & Cooke with the use of OAPA because Duerksen & Wilkinson discovered that OAPA has the advantages of specificity, water solubility, negative charge, and linking ability (see Abstract).

With respect to claim 2, Duerksen & Wilkinson teach a method comprising phenylglyoxal (see Abstract, "4-(Oxoacetyl)phenoxyacetic acid (OAPA)") (see also, p. 450, col. 1, "phenylglyoxal").

With respect to claims 3-4, Balint & Cooke teach a method wherein α -amino groups are modified with a dye (see p. 20, line 6).

With respect to claims 5-7, Balint & Cooke teach a method comprising an antibody to ADMA (see p. 7, lines 18-20) that is detectably labeled (see p. 16, lines 23-26).

With respect to claim 8, Balint & Cooke teach a method wherein HPLC is used (see p. 19, lines 27-28).

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Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balint & Cooke (WO 98/49199) and Duerksen & Wilkinson, 160 ANAL. BIOCHEM. 444 (1987), as applied to claim 1, and further in view of Fishman et al. (US 5,318,680).

Balint & Cooke and Duerksen & Wilkinson teach a method of detecting ADMA in a sample as substantially described supra. The aforementioned references do not teach a method using capillary electrophoresis.

However, Fishman et al. teach the use of capillary electrophoresis for derivatizing and separating sample components (see Abstract). Therefore, it would have been obvious for a person of ordinary skill in the art to perform the method of detecting ADMA in a sample, as taught by Balint & Cooke and Duerksen & Wilkinson, with the use of capillary electrophoresis because Fishman et al. discovered that on-column derivatization results in fast kinetics and high yield (see Abstract).

Conclusion

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
Art Unit 1641

djv


LONG V. LE
SUPERVISORY PATENT EXAMINER
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02/04/05